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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/854,065	05/11/2001	Timothy J. Barberich	0701.113C	8299

23405 7590 04/25/2003

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EXAMINER

DENTZ, BERNARD I

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 04/25/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/854,065

Applicant(s)

BARBERICH ET AL.

Examiner

Bernard Dentz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2002 and 13 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13-25 are again rejected under 35 U.S.C. 102(b) as being anticipated by Larsson et al, WO 96/02535 cited by applicants for basically the reasons of record in Paper No. 5.

To elaborate it discloses in Ex. 21 a method for preparing the S(-) enantiomer of lansoprazole by oxidizing the corresponding racemic thio compound. The above enantiomer as obtained as an oil with an optical purity of 99.5% i.e.. At page 1, lines 19-26 the same is disclosed as useful in inhibiting gastric secretion. This is another way of saying that the above enantiomer is useful in treating humans with conditions involving hyper gastric *secretion*.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Larsson et al, supra.

In case the anticipation rejection over this reference is overcome the Examiner also alleges that it since there is no actual example in said reference of treating a human having a condition involving hyper gastric secretion with the instant enantiomer

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that an obvious rejection pertains in view of the reference's teachings which are set out above.

Further claims 18-20 and 25 recite treatment of conditions in humans that are known by the ordinarily skilled to involve increase gastric hypersecretion. Claims such as 15, 16 etc. relating to dosage form or amount are within the normal parameters or forms commonly used in the art. Thus these claims are obvious given the background of the art.

Claims 17-20 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Larsson et al, supra in view of Garnett cited by applicants.

The former is used as above. The latter discloses that lansoprazole is used to treat gastroesophageal reflux disease, which claims 17-20 relate to, and also that it is used to treat Zollinger-Ellison syndrome. See p. 1425 under Acid Related Disorders. Thus it would have been obvious to use the (-) enantiomer disclosed by Larsson et al to treat these conditions.

26-29 are
Claim^s *^* rejected under 35 U.S.C. 103(a) as being unpatentable over Larsson et al, supra in view of Hasselkus, US Patent 5,714,505.

These claims recite the treatment of psoriasis using the instant enantiomer. The former reference is used as above. Since the latter at col. 3, line 20 discloses that lansoprazole is useful in treating psoriasis the use of the instant enantiomer of Larsson et al for the same purpose would have been obvious.

Applicants' arguments in Paper No. 6 and 8 (including the unsigned Affidavit Under Rule 132) are unconvincing. As far as the Examiner is concerned the Larson et

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al reference represents an unclearable legal hurdle to patentability given its apparent synthesis and teaching of utility for S(-) lansoprazole.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bernard Dentz whose telephone number is (703) 308-4544. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703) 308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 3084556 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Dentz/LR
April 24, 2003



BERNARD DENTZ
PRIMARY EXAMINER
GROUP 1600